

## UNITED STATES PATENT AND TRADEMARK OFFICE

MAR 1 0 2010

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

George W. Johnston Hoffmann-La Roche Inc. Patent Law Department 340 Kingsland Street Nutley, New Jersey 07110

In Re: Patent Term Extension
Application for
U.S. Patent No. 6,583,272

Dear Mr. Johnston:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 6,583,272 for a period of 445 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to patent expiration dates.

Inquiries regarding this communication should be directed to Raul Tamayo by telephone at (571) 272-7728, or by e-mail at raul.tamayo@uspto.gov.

Mary C. Tvil

Legal Advisor

Office of Patent Legal Administration Office of the Associate Commissioner for Patent Examination Policy

cc:

Office of Regulatory Policy Food and Drug Administration 10903 New Hampshire Ave., Bldg. 51, Rm. 6222 Silver Spring, MD 20993-0002 RE: MIRCERA® (methoxy polyethylene glycol-epoetin beta) FDA Docket No.: FDA-2008-E-0107

Attention: Beverly Friedman

## UNITED STATES PATENT AND TRADEMARK OFFICE

(12) CERTIFICATE EXTENDING PATENT TERM UNDER 35 U.S.C. § 156

(68) PATENT NO. : 6,583,272

(45) ISSUED : June 24, 2003

(75) INVENTOR : Pascal Sebastian Bailon

(73) PATENT OWNER : Hoffmann-La Roche Inc.

(95) PRODUCT : MIRCERA® (methoxy polyethylene

glycol-epoetin beta)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 6,583,272 based upon the regulatory review of the product MIRCERA® (methoxy polyethylene glycol-epoetin beta) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94) 445 days

from August 26, 2020, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).



I have caused the seal of the United States Patent and Trademark Office to be affixed this 25th day of February 2010.

David J. Kappos

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office